APPENDIX A

PENDING CLAIMS

1. (WITHDRAWN) A method of protocol development for a clinical trial, comprising the steps of:

identifying a clinical trial target reflecting a goal of the clinical trial;

determining desired evaluability data categories to be gathered pertaining to a participant in the clinical trial, wherein an evaluability data of at least one of the evaluability data categories is used to determine the desirability of retaining the participant in the trial or incorporating the participant in at least one result of the clinical trial.

2. (WITHDRAWN) The method of protocol development of claim 1, wherein the evaluability data is used during the trial to determine the desirability of retaining the participant in the trial or incorporating the participant in the trial results.

3. (WITHDRAWN) The method of protocol development of claim 1, further comprising the step of generating at least one compliance enhancing feature, wherein the compliance enhancing feature includes a question to be posed to a user to determine a reason for non-compliance.

4. (ORIGINAL) A method of determining preferred targets for subject compliance, comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data; and

generating at least one preferred compliance threshold by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data.

5. (ORIGINAL) The method of determining preferred targets for subject compliance of claim 4, further comprising the steps of:

obtaining subject compliance information; and

comparing the subject compliance information to the at least one preferred compliance threshold to determine if action is needed.

6. (ORIGINAL) The method of determining preferred targets for subject compliance of claim 5, further comprising the step of prompting action if the step of comparing indicates that action is needed.

7. (ORIGINAL) The method of determining preferred targets for subject compliance of claim 5, wherein the step of obtaining includes use of a portable electronic device capable of displaying information and receiving and storing input from a user.

8. (ORIGINAL) A method of monitoring subject compliance, comprising the steps of:

providing historical subject compliance data;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information;

obtaining the subject compliance information;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

9. (ORIGINAL) The method of predicting subject noncompliance of claim 8, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

10. (ORIGINAL) The method of determining subject compliance of claim 9, wherein the step of providing employs at least one database containing the historical protocol data.

11. (ORIGINAL) The method of determining subject compliance of claim 8, wherein the step of obtaining includes using a portable electronic device capable of displaying information and receiving and storing input from a user.

12. (ORIGINAL) The method of determining subject compliance of claim 8, wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees.

13. (ORIGINAL) The method of determining subject compliance of claim 8, wherein the step of providing employs at least one database containing the historical subject compliance data.

14. (ORIGINAL) A method of determining subject compliance, comprising the steps of:

providing historical subject compliance data and historical protocol data;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

15. (ORIGINAL) The method of determining subject compliance of claim 14, wherein the step of obtaining includes using a portable electronic device capable of displaying information and receiving and storing input from a user.

16. (ORIGINAL) A method of predicting subject noncompliance, comprising the steps of:

providing historical subject compliance data;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule;

obtaining subject compliance information;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed.

17. (ORIGINAL) The method of predicting subject noncompliance of claim 16, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

18. (ORIGINAL) The method of determining subject noncompliance of claim 17, wherein the step of providing employs at least one database containing the historical protocol data.

19. (ORIGINAL) The method of predicting subject noncompliance of claim 16, wherein the step of obtaining includes the use of a portable electronic device capable of displaying information and receiving and storing input from a user.

20. (ORIGINAL) The method of predicting subject noncompliance of claim 16, further comprising the step of creating an evaluability database adapted to store data related to subject compliance.

21. (ORIGINAL) The method of predicting subject noncompliance of claim 16, further comprising the step of providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database.

22. (ORIGINAL) The method of predicting subject noncompliance of claim 21, wherein the evaluability database is tailored to a condition affecting the subject.

23. (ORIGINAL) The method of determining subject noncompliance of claim 16, wherein the step of providing employs at least one database containing the historical subject compliance data.

24. (ORIGINAL) A method of enhancing subject compliance, comprising the steps of:

providing historical subject compliance data;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule;

obtaining subject compliance information; and

comparing the subject compliance information to the at least one decision rule to determine if affirmative action is warranted.

25. (ORIGINAL) The method of predicting subject noncompliance of claim 24, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

26. (ORIGINAL) The method of enhancing subject compliance of claim 24, further comprising the step of prompting action if the step of comparing indicates that affirmative action is warranted.

27. (ORIGINAL) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes reducing a number of occurrences of the step of obtaining subject compliance information.

28. (ORIGINAL) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes increasing a number of occurrences of the step of obtaining subject compliance information.

29. (ORIGINAL) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes giving a reward.

30. (ORIGINAL) The method of enhancing subject compliance of claim 24, wherein the step of obtaining includes the use of a portable electronic device capable of displaying information and receiving and storing input from a user.

31. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a user; and

an alarm electrically coupled to the portable electronic device and having varying alarm tones, wherein the varying alarm tones are emitted by the alarm if the user does not comply with a predetermined protocol for providing the input to the portable electronic device.

32. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a user; and

a tactile alarm electrically coupled to the portable electronic device to prompt the user to provide the input to the portable electronic device.

33. (WITHDRAWN) The compliance monitoring device of claim 32, wherein the portable electronic device is adapted to interface with a computer to exchange data with the computer.

34. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a participant in the clinical trial;

wherein the portable electronic device examines the input and reviews the input for inconsistencies.

35. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a participant in the clinical trial;

wherein the portable electronic device increases an amount of prompting of the input from the participant upon an automated determination that the participant does not comply with a predetermined protocol for providing the input to the portable electronic device.

36. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a participant in the clinical trial;

wherein the portable electronic device decreases an amount of prompting of the input from the participant upon an automated determination that the participant has reported a predetermined number of events other than in response to the prompting by the portable electronic device.

37. (WITHDRAWN) A compliance monitoring device for use in clinical trials, comprising:

a portable electronic device capable of displaying information and receiving and storing input from a user;

wherein the user is provided feedback based on the determination of whether the user has followed a predetermined protocol for providing the input to the portable electronic device.

38. (WITHDRAWN) The compliance monitoring device of claim 37, wherein the portable electronic device determines whether the user has followed a predetermined protocol for providing the input to the portable electronic device more closely as a function of having received the feedback.

39. (WITHDRAWN) A method for compliance monitoring of a subject in a clinical trial, comprising the steps of:

providing a portable electronic device capable of displaying information to the subject and receiving input from the subject and storing the input;

accepting the input from the subject; and

activating a tactile alarm if the subject does not comply with a predetermined protocol for providing the input to the portable electronic device.

40. (WITHDRAWN) The method of claim 39, wherein the portable electronic device is adapted to interface with a computer to exchange data with the computer.

41. (WITHDRAWN) A method for compliance monitoring of a subject in a clinical trial, comprising the steps of:

providing a portable electronic device capable of displaying information to the subject and receiving input from the subject and storing the input;

accepting the input from the subject; and

activating a tactile alarm if the input is not correct.

42. (WITHDRAWN) A method for compliance monitoring of a subject in a clinical trial, comprising the steps of:

providing a portable electronic device capable of displaying information to the subject and receiving input from the subject and storing the input;

accepting the input from the subject; and

increasing an amount of prompting of the input from the subject upon an automated determination that the subject does not comply with a predetermined protocol for providing the input to the portable electronic device.

43. (WITHDRAWN) A method for compliance monitoring of a subject in a clinical trial, comprising the steps of:

providing a portable electronic device capable of displaying information to the subject and receiving input from the subject and storing the input;

accepting the input from the subject; and

decreasing an amount of prompting of the input from the subject upon an upon an automated determination that the participant has reported a predetermined number of events other than in response to the prompting by the portable electronic device.

44. (WITHDRAWN) A method for conducting a clinical trial, comprising the steps of:

gathering subject compliance data;

storing subject compliance data in an evaluability database; and

providing access to said evaluability database to a sponsor of said clinical trial.

45. (WITHDRAWN) The method of claim 44, wherein said gathering step involves a portable electronic device capable of displaying information to the subject and receiving input from the subject and storing the input.

46. (WITHDRAWN) In an electronic device that interacts with a participant of a clinical trial, a method comprising:

displaying information to the participant and prompting input from the participant;

accepting the input from the participant; and

decreasing an amount of prompting of the input from the participant upon an upon an automated determination that the participant has reported a predetermined number of events other than in response to the prompting by the portable electronic device.

47. (WITHDRAWN) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

identifying a clinical trial target reflecting a goal of the clinical trial;

determining desired evaluability data categories to be gathered pertaining to a participant in the clinical trial, wherein an evaluability data of at least one of the evaluability data categories is used to determine the desirability of retaining the participant in the trial or incorporating the participant in at least one result of the clinical trial.

48. (ORIGINAL) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data; and

generating at least one preferred compliance threshold by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data.

49. (ORIGINAL) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information;

obtaining the subject compliance information;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

50. (ORIGINAL) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data and historical protocol data;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

51. (ORIGINAL) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule;

obtaining subject compliance information;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed.

52. (ORIGINAL) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule;

obtaining subject compliance information; and

comparing the subject compliance information to the at least one decision rule to determine if affirmative action is warranted.

53. (WITHDRAWN) A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

displaying information to the participant and prompting input from the participant;

accepting the input from the participant; and

decreasing an amount of prompting of the input from the participant upon an upon an automated determination that the participant has reported a predetermined number of events other than in response to the prompting by the portable electronic device.